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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,424	11/17/2003	Gai Ling Li	25350	4527

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,424	LI ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/17/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections – 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-8 and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear by the wording of the claims what exactly the donor phase is. The wording in claim 7 seems to read as a physical portion of the iontophoretic device while claims 8 and 11-16 seems to read as the mixture of the drug and the chloride salt.

Claims 1-8 and 10-16 provides for the use of a composition comprising rotigotine and at least one chloride salt, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. For compact prosecution, it is assumed that claims 1-8 and 10-16 are drawn to a method of making a pharmaceutical composition.

Claim Rejections – 35 USC 101

Claims 1-8 and 10-16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process

claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Therefore, claims 1-8 and 10-16 are being treated as a method of making a pharmaceutical composition claims comprised of rotigotine and at least one chloride salt. Furthermore, the intended use of a composition claim is not given any patentable weight.

Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-7 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauterback et al. (US PG-Pub 2003/0027793) in view of Panchagnula et al. (Curr Op Chem Biol 2000, 4:468-473) and Suzuki et al. (US Patent 6,416,503).

Lauterback et al. teach the preparation of a transdermal patch therapeutic system containing rotigotine hydrochloride as the active ingredient (meeting the limitations of claims 1-3 and 6-8; paragraph 0016, 0025, 0026, 0031 and 0038). It is further taught that the transdermal patch therapeutic system is useful to treat Parkinson's disease (paragraph 0030).

Lauterback et al. does not teach treating Parkinson's disease transdermally by application of an iontophoretic device, the concentration of rotigotine, the concentration of the chloride salt with a pH of 4 to 6.5 or the specific chloride salts as claimed in claims 4 and 5.

Panchagnula et al. teaches that iontophorectic transport involves movement of molecules across the skin (see second and third paragraph in column 2, page 468). Table 1 shows iontophoretic products under development, one of which includes a wearable iontophoretic patch (page 469). In addition it is further taught that a hydratable gel pad is also useful (last paragraph page 470).

Suzuki et al. teach iontophoretic drug devices that contain sodium chloride (Col. 7, lines 1-3).

Furthermore, it is obvious to vary and/or optimize the amount of rotigotine, amount of chloride salt and pH provided in the composition, according to the guidance provided by Lauterback et al. and Suzuki et al. to provide a composition having the desired properties such as the desired concentrations of rotigotine, chloride salt and pH in order to effectively construct an iontophoretic device that will effectively transfer drug through the skin. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Lauterback et al., which teach a

method of making a transdermal patch containing rotigotine hydrochloride to treat Parkinson's disease, with the teachings of Panchagnula et al., which teach transdermal delivery of drugs via iontophoresis, including a patch and Suzuki et al. which teach the use of sodium chloride in an iontophoretic device. One would have been motivated to use iontophoresis as a method to transdermally deliver rotigotine hydrochloride because it is an efficient method to deliver drugs and cost effective (as taught by Panchagnula et al.) and to add sodium chloride in an effort to further improve drug delivery (as taught by Suzuki et al.).

Conclusions

Claims 5, 8 and 11-16 are rejected because they are dependent on rejected claims. No claims allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor